UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,857	11/07/2000	Kathryn Armour	620-117	5675

23117 7590 01/13/2006

NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
HUYNH, PHUONG N	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 01/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/674,857	ARMOUR ET AL.	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-29,31-33,37-42 and 46-67* is/are pending in the application.

4a) Of the above claim(s) *31* is/are withdrawn from consideration.

5)☒ Claim(s) *32,33,37,41,42 and 46* is/are allowed.

6)☒ Claim(s) *16-29,38,39,47,48 and 50-67* is/are rejected.

7)☒ Claim(s) *40 and 49* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/26/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/25/05 has been entered.

2. Claims 16-29, 31-33, 37-42 and 46-67 are pending.

3. Claim 31 stands withdrawn from further consideration by the examiner, 37 C.F.R. 1.142(b) as being drawn to non-elected inventions.

4. Claims 16-29, 32-33, 37-42 and 46-47, drawn to a binding molecule, an isolated nucleic acid encoding said binding molecule, a process of making and using said binding molecule, are being acted upon in this Office Action.

5. The specification is objected to for failing to provide antecedent basis for "neutrophil antigen" recited in claims 27, 38 and 47, "coronary artery occlusion" recited in claim 62 and "HDN" recited in claims 28 and 62.

6. Claims 40 and 49 are objected to because "a binding molecule" should have been "the binding molecule" for said dependent claims.

7. Applicant is advised that should claim 21 be found allowable, claim 55 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

9. Claim 21-22, 55-56 and 66-67 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

The omitted steps in claims 21 and 55 are: culturing the host cell transformed with the vector comprising the nucleic acid encoding the binding molecule of claim 17, and isolating the binding molecule from cell culture.

The omitted steps in claim 66 are: culturing the host cell transformed with the vector comprising the nucleic acid encoding the binding molecule of claim 51, and isolating the binding molecule from cell culture.

10. Claims 16-20, 23-29, 38-39, 47-48, 50-54, and 57-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

"An isolated nucleic acid comprising **a** nucleotide ... in claim 32...DNA" as recited in claim 16 is indefinite. The nucleic acid encompasses any nucleic acids that comprise the full-length sequence or any portion of a nucleotide sequence encoding the effector domain of the binding molecule as claimed in claim 32. The specification does not disclose any nucleic acid comprising a nucleotide sequence encoding any portion of the effector domain of the binding molecule. One of ordinary skill in the art cannot appraise the metes and bound of the claimed invention. It is suggested that claim 16 be amended to recite "An isolated nucleic acid comprising *the* nucleotide sequence encoding the effector domain of the binding molecule as claimed in claim 32, wherein said nucleic acid is DNA". Likewise, the same reasoning applies to claims 17, 50 and 51 and should be amended accordingly.

The "HPA" in claims 27, 38 and 47 is indefinite and ambiguous. One of ordinary skill in the art cannot appraise the metes and bound of the claimed invention. While abbreviation can be used in a claim, to avoid potential confusion, the first recitation of the abbreviation should be preceded by the full terminology, such as human platelet alloantigen (HPA-1a), for example.

The "GBM collagen" in claims 27, 38 and 47 is indefinite and ambiguous. While abbreviation can be used in a claim, to avoid potential confusion, the first recitation of the abbreviation should be preceded by the full terminology, such as glomerular basement membrane (GBM), for example. Further, the specification on page 20 discloses only collagen type IV mediated anti-glomerular basement membrane disease (Goodpastures's syndrome). The specification does not any other collagen as autoantigen in anti-glomerular basement membrane disease. One of ordinary skill in the art cannot appraise the metes and bound of the claimed invention.

The "HDN" recited in claim 28 part vi) and claim 62 part vi) should have been "hemolytic disease" since the specification does not disclose the abbreviation HDN stands for. One of ordinary skill in the art cannot appraise the metes and bound of the claimed invention.

The "HPA alloantigen of platelets" and "HPA-1a" in claims 27, 38 and 47 is in improper Markush group. This is because "HPA-1a" is "HPA alloantigen of platelets". It is suggested that claim 27 be amended to recite the method of claim 23 wherein the target molecule is selected from the group consisting of the RhD antigen of red blood cells, the human platelet alloantigen HPA-1a, a neutrophil antigen, a T cell receptor, an integrin, a glomerular basement membrane type IV collagen, a Der P1 antigen, VAP-1, laminin, Lutheran, platelet glycoprotein VI, and platelet glycoprotein Ia/IIa.

Likewise, it is suggested that claim 38 be amended to recite the binding molecule as claimed in claim 23 wherein the target molecule is selected from the group consisting of the RhD antigen of red blood cells, the human platelet alloantigen HPA-1a, a neutrophil antigen, a T cell receptor, an integrin, a glomerular basement membrane type IV collagen, a Der P1 antigen, VAP-1, laminin, Lutheran, platelet glycoprotein VI, and platelet glycoprotein Ia/IIa.

As for claim 47, it is suggested that claim 47 be amended to recite the binding molecule as claimed in claim 41 wherein the target molecule is selected from the group consisting of the RhD antigen of red blood cells, the human platelet alloantigen HPA-1a, a neutrophil antigen, a T cell receptor, an integrin, a glomerular basement membrane type IV collagen, a Der P1 antigen, VAP-1, laminin, Lutheran, platelet glycoprotein VI, and platelet glycoprotein Ia/IIa.

The "...binding domain is selected from that of anti-CD52 antigen *found on human lymphocytes*" in claims 39 and 48 is indefinite and ambiguous because only CD52

antigen is found on human lymphocytes, not the binding domain of the antibody. It is suggested that claim 39 be amended to recite the binding molecule as claimed in claim 38 wherein the antibody is selected from the group consisting of anti-CD52, anti-RhD, anti-HPA-1a, anti-VAP-1, murine anti-α3 (IV) NC1, anti-CD3, anti-Der pI, anti-laminin and anti-lutheran. Likewise, claim 48 be amended to recite the binding molecule as claimed in claim 47 wherein the antibody is selected from the group consisting of anti-CD52, anti-RhD, anti-HPA-1a, anti-VAP-1, murine anti-α3 (IV) NC1, anti-CD3, anti-Der pI, anti-laminin and anti-lutheran.

"A method of binding a target molecule, which target molecule is capable of being bound by said binding molecule" in claims 23 and 57 is indefinite and ambiguous. The specification on page 13 and 17 discloses a method of competitively inhibiting undesirable autoantibody-autoantigen or alloantibody-alloantigen interaction, the method comprising contacting the binding molecule of claim 41 under conditions that allow binding to the target molecule wherein the binding inhibits the binding of autoantibody or alloantibody from binding to the target antigen.

"The method of claim 57 for treatment of a patient" in claim 62 is ambiguous and indefinite because the method of binding now suddenly becomes a method of treating a patient with various diseases. Likewise, the same reasoning applies to claim 28.

11. Claims 32-33, 37, 41-42 and 46 are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (571) 273-8300.

13. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For

more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phuong N. Huynh, Ph.D.
Patent Examiner
Technology Center 1600
January 6, 2006

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600